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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,330	03/26/2004	Stefan Vilsmeier	SCHWP0187USA	1366
<div>7590 06/04/2007 Don W. Bulson RENNER, OTTO, BOISSELLE & SKLAR, LLP Nineteenth Floor 1621 Euclid Avenue Cleveland, OH 44115-2191</div>			<div>EXAMINER ROZANSKI, MICHAEL T</div>	
			<div>ART UNIT 3768</div>	<div>PAPER NUMBER</div>
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,330

Applicant(s)

VILSMEIER ET AL.

Examiner

Michael Rozanski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/14/07 have been fully considered but they are not persuasive. With respect to claim 19, the USC 101 rejection is not withdrawn because the claimed invention is directed to non-statutory subject matter. Claim 19 recites a "computer program" that imparts the method of claim 1. However, the claim does not require that the program reside on a computer readable medium, or that it is actually on a computer. A "computer program" per se is not an apparatus, method, a product or a composition of matter. Rather, a computer program is an intangible thing, and thus non-statutory. This type of information is considered "functional descriptive material and is non-statutory per se (see MPEP 2106(IV)(B)(1)(a)). A computer program (or method steps performed by a computer program) would be statutory if it is claimed as being recorded on a "computer readable medium" (as opposed to a "computer program"), or a "computer memory". The examiner suggests incorporating the limitations of a "computer readable medium" to overcome this rejection.

With respect the Van Der Brug (US 5,954,648) and Schwiekard et al (US Pub 2004/0082849) references, it is argued that use of a 3D generic model is not disclosed. However, the examiner holds that CT image data in '648 (col. 4, lines 9-14) and the image data set of '849 (para. [0050]) does suggest use of a 3D generic model, as both instances demonstrate 3D usage with patient-specific body structure data for navigational purposes.

With respect to Simon et al (US 6,470,207), applicant argues that patient-specific body data is not used and instead uses atlas, or non-patient-specific data. The examiner respectfully disagrees, as the patent '207 clearly describes five examples in which the invention can be utilized, all of which use three-dimensional patient specific data and not atlas data (col 15, line 30-col. 18, line 64). Further, it is also disclosed that adapting is accomplished by linking the 3D model to various forms of existing patient-characteristic data (col. 16, line 40-col. 17, line 23).

With respect to newly added claims 21-23, Simon et al substantially teach all features as described below, including registering the x-ray images and superimposing the images with the model. Simon et al also teaches deforming atlas data wherein it would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated this teaching to achieve the claimed deforming of patient specific data in order to better correspond to the patient (col. 18, lines 53-63).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims to computer data structures and programs must typically pass two threshold tests under 35 U.S.C. 101. They must be eligible subject matter and they must produce a useful, concrete and tangible result.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 6, 7, and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by ***Van Der Brug*** (US 5,954,648).

Claims 1, 3, 6, 7, and 12-19: Van Der Brug discloses an image guided surgery system that comprises a position detection system, including a camera unit 1 with one or more cameras 10 and a data processor 2 (col. 3, lines 57-60). The data processor includes a computer 21 that, on the basis of image signals, computes the position of the surgical instrument relative to the patient 12 undergoing operation (col. 4, lines 2-6). The computer also computes the corresponding position of the instrument 11 in an earlier generated image such as a CT image, wherein the CT image data (i.e. a digital reconstructed radiograph) is stored in storage medium 23 (col. 4, lines 9-13). The image data suggests 3D usage with patient-specific body structure data for navigational purposes. Further, computer 21 calculates the transformation matrix, which connects the positions in space of fiducial markers to the corresponding positions of the images of the markers in the previously generated images (col. 4, lines 20-26). In the

alternative, the computer may include a program to calculate the coordinates of the position of the surgical instrument with respect to a fixed reference system, while the image processor 22 is arranged to convert those coordinates to the corresponding position in the image (col. 4, lines 30-34).

5. Claims 1-19 and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by *Simon et al* (US 6,470,2007).

Claims 1-19 and 21-22: Simon et al. disclose a navigational guidance system via computer-assisted fluoroscopic imaging including a fluoroscopic imaging device 100 with an x-ray source for generating x-rays that propagate through patient 110 and calibration target 106, and into x-ray receiving section 105 (col. 5, lines 50-52). Images are forwarded to computer 120, which provides facilities for displaying, saving, or digitally manipulating the images. Furthermore, 3D images, such as pre-acquired patient specific CT/MR data set 124 may also be manipulated by computer 120 and displayed by monitor 121 (col. 5, lines 63 – col. 6, line 5). Given a 3D CT data set, a stimulated x-ray image can also be generated using digitally reconstructed radiography (DRR) (col. 16, lines 45-47).

The image formation process in the imaging system utilizes a geometric projective transformation which maps lines in the imager's field of view to points in the image. For example, image 300 comprises pixels, wherein every pixel has a corresponding 3D line in the imager's field of view. The complete mapping between image pixels and corresponding lines governs the projection of objects within the field of

view into the image. Further, it is necessary to estimate the projective transformation which maps lines in the field of view to pixels in the image, and vice versa, when performing computer assisted navigational guidance (col. 6, lines 43-62).

A tracking sensor 130, which is linked to computer 120, detects and locates in 3D space surgical instruments (col. 7, lines 45-48). A graphical representation of instrument 140 may then be overlaid on the fluoroscopic images, wherein the graphical representation is an iconic representation of where the actual surgical instrument would appear within the acquired image (col. 9, lines 29-35).

A clinical example is disclosed wherein a physician places a tracking sensor marker on each of bone fragments 1201 and 1202 and acquires fluoroscopic images in an orthopaedic bone alignment procedure. A computer 120 processes the acquired image to obtain positional location information and to calibrate the image. After image acquisition, computer 120 uses image detection and extraction techniques to delineate the boundaries of the bone fragments in the images. Suitable edge detection algorithms for generating contours 1203 and 1204, which may be graphically superimposed by computer on the image. The physician may input this correspondence into the computer (manually), or the computer may automatically identify the correspondence between the image contours and the bone fragments (Column 13). Note that before overlaying the 3D image with graphical representations of surgical instruments, the correspondence between points in the 3D image and points in the patient's reference frame are determined through 2D/3D registration (col. 14, lines 32-43).

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Five examples are also used to clearly demonstrate instances in which the invention can be utilized, all of which use three-dimensional patient specific data and not atlas data (col 15, line 30-col. 18, line 64). Further, it is also disclosed that adapting is accomplished by linking the 3D model to various forms of existing patient-characteristic data (col. 16, line 40-col. 17, line 23).

6. Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by **Schweikard et al** (US Pub 2004/0082849).

Claims 1-19: Schweikard et al. disclose a method for navigating in the interior of the body using 3D visualized structures including a localization computer 20 of a tracking system that calculates the actual spatial position of the surgical instrument 14 provided with the marker 16 from the signals received by the infrared detector 18 (para. [0041]). A central computer 22 generates a 3D approximation model of a bone 12 from the intraoperatively obtained 2D images and represents the approximation model, a geometric structure to be visualized and also the relative position of the surgical instrument with respect to the bone or to the geometric structure, graphically on the viewing screen 24 (para. [0044]). The approximation model 52 may be improved by taking into account a preoperatively determined MR data set of the bone, wherein the model can be calculated with the aid of MR tomography (para. [0050]). Furthermore, a method for obtaining 2D x-ray contours and 3D nuclear spin data is disclosed (para. [0052]). The navigation system also includes characterization of bone by semicircular

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outline 78, 78' of the head of the bone, which is marked manually or by means of software (automatically) (para. [0063]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over ***Simon et al.***

Claim 23: Simon et al teach of deforming atlas data wherein it would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated this teaching to achieve the claimed deforming of patient specific data in order to better correspond to the patient (col. 18, lines 53-63).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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